



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,853	04/02/2004	Jeffrey C. Garland	115622	2875
25944 7590 03/18/2009 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
BEISNER, WILLIAM H				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
03/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,853

Applicant(s)

GARLAND ET AL.

Examiner

WILLIAM H. BEISNER

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50, 53 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50, 53 and 56-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 9, 11, 17-20, 24-26, 27, 29, 32, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (US 3,810,367).

With respect to claim 1, the reference of Peterson discloses an apparatus for holding an organ that includes an organ transporter (6,7,14); a portable housing (2) having one or more heat transfer surfaces; a compartment (12) within the transporter (6,7,14) having one or more heat transfer surfaces (11) arranged on an outer surface of the compartment to transfer heat between a cooling source (9,10) contained within the compartment and at least part of one of the one or more heat transfer surfaces of the portable housing (2), the compartment being liquid-tight and

preventing contact between a liquid contained within the compartment and the portable housing (See Figure 1). In the absence of further positively recited structure, the bottom of the portable housing (2) is considered to provide an organ supporting surface configured to support an organ within the portable housing. The portable housing and the transporter are configured such that the portable housing is received within the transporter so as to contact the heat transfer surfaces (See Figure 1).

With respect to claim 2, the cooling source is a cooling fluid (10).

With respect to claims 3, 17, 32 and 33, in the absence of further positively recited structure, the support surface (bottom) is considered to be configured so as to allow effluent fluid to pass through the organ and collect fluid.

With respect to claims 4-7 and 27, the surfaces of the portable housing and transporter are considered to have complementary configurations wherein the heat transfer surfaces are in contact (See Figure 1).

With respect to claims 9, 11, 29 and 35, the complementary configurations that mate are in the form of a truncated cone (See Figure 1) and are non-planar surfaces.

With respect to claims 18, 19 and 24-26, the fluid is ice and/or water (9,10).

With respect to claim 20, use of the device as disclosed by the reference of Peterson meets the steps recited in claim 20.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1797

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(e) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 8, 10, 28 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367).

The reference of Peterson has been discussed above.

Claims 8, 10, 28 and 34 differ by reciting that the heat transfer surfaces are in the shape of a trapezoid and/or include planar surfaces.

With respect to the shape of the surfaces, it would have been obvious to one of ordinary skill in the art to provide surfaces within the transport container that match the surfaces of the material holding container while maintaining the transfer efficiency of the system. Note, changes in shape are not a patentable distinction (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)).

8. Claims 12, 13, 16, 21-23, 30, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al.(US 3,995,444).

The reference of Peterson has been discussed above.

Claims 12, 13, 16, 22, 23, 30, 36 and 37, differ by reciting that the portable housing includes openings and/or tubing that allow the tubing to pass through the openings and be connected to the organ and allow the tubing to be mated with the portable housing when the housing is removed from the compartment.

Both of the references of Fahy and Clark et al. disclose that it is known in the art of organ perfusion/transportation to provide a portable housing with openings that allow tubing to pass through the openings and be connected to the organ and allow the tubing to be mated with the portable housing when the housing is removed from the compartment (See Figure 1 of Fahy and the Figure of Clark et al.).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with openings and/or tubes for

communication with an organ contained within the housing for the known and expected result of allowing perfusion of the organ during the storage and/or transport thereof.

Claim 21 differs by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the system without removal of the organ from the housing would have been obvious for the known and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

9. Claims 14, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of Reviel (US 3,713,302).

The reference of Peterson has been discussed above.

Claims 14, 38 and 39 differ by reciting that the device includes a heater.

The reference of Reviel discloses that it is known in the art of cooling to employ a thermo-electric cooling source that can function as a cooling source or a heating source (See column 2, lines 2-22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a thermo-electric device in the system of the primary reference for the known and expected result of providing improved temperature control when compared to the use of ice or ice packs (See column 1, lines 35-55).

10. Claims 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of Thomson (US 1,369,367).

The reference of Peterson has been discussed above.

Claims 15 and 31 differ by reciting that the portable housing includes a handle that is accessible when the portable housing is mated with the compartment.

The reference of Thomson discloses that it is known in the art to provide a portable housing (2,4) with a handle (6) so as to facilitate removal of the housing from a transportation or storage device (10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with a handle for the known and expected result of facilitating the removal of the portable housing from the transportation or storage device.

11. Claims 40-50 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al.(US 3,995,444) taken further in view of Thomson (US 1,369,367).

The combination of the references of Peterson and either Fahy or Clark et al. has been discussed above.

Claim 40 differs by reciting that the portable housing includes a handle that is accessible when the portable housing is mated with the compartment.

The reference of Thomson discloses that it is known in the art to provide a portable housing (2,4) with a handle (6) so as to facilitate removal of the housing from a transportation or storage device (10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with a handle for the known and expected result of facilitating the removal of the portable housing from the transportation or storage device.

With respect to claim 41, the cooling source is a cooling fluid (10).

With respect to claims 42 and 56, in the absence of further positively recited structure, the support surface (bottom) is considered to be configured so as to allow effluent fluid to pass through the organ and collect fluid.

With respect to claims 43-46, the surfaces of the portable housing and transporter are considered to have complementary configurations wherein the heat transfer surfaces are in contact (See Figure 1).

With respect to claims 48 and 50, the complementary configurations that mate are in the form of a truncated cone (See Figure 1) and are non-planar surfaces.

With respect to the shape of the surfaces of claims 47 and 49, it would have been obvious to one of ordinary skill in the art to provide surfaces within the transport container that match the

surfaces of the material holding container while maintaining the transfer efficiency of the system.

Note, changes in shape are not a patentable distinction (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)).

With respect to claims 57 and 58, the fluid is ice and/or water (9,10).

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al.(US 3,995,444) in view of Thomson (US 1,369,367) taken further in view of Reviel (US 3,713,302).

The combination of the references of Peterson and either Fahy or Clark et al. in view of Thomson has been discussed above.

Claim 53 differs by reciting that the device includes a heater.

The reference of Reviel discloses that it is known in the art of cooling to employ a thermo-electric cooling source that can function as a cooling source or a heating source (See column 2, lines 2-22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a thermo-electric device in the system of the primary reference for the known and expected result of providing improved temperature control when compared to the use of ice or ice packs (See column 1, lines 35-55).

13. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al.(US 3,995,444) in view of McKelvey et al.(EP 0 376 763).

The combination of the references of Peterson and either Fahy or Clark et al. has been discussed above.

Claim 59 differs by reciting that the device includes an organ perfusion devcie.

The reference of McKelvey et al. discloses that a portable housing (31) can be inserted into a parent device (30) without compromising sterility and that the portable housing (31) allows transfer of an organ contained therein from one transportation device to another and specifically recites the use of a separate base unit and transportation unit (See column 6, lines 1-19).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to provide both a base unit and a separate transportation unit for use with the portable housing (31) as suggested by the reference of McKelvey et al. When providing a base unit and separate transportation unit as suggested above, the portable housing would be capable of (1) holding the organ independently from either of the organ perfusion (base unit) or the transporter (transportation unit); (2) being received by the transporter for transport of the organ; (3) being separately received by the organ perfusion apparatus for perfusion of the organ; and (4) allow perfusion, storage, and transport of the organ without removal of the organ from the portable housing. Note the transportation unit suggested and discussed above would be a portable organ perfusion apparatus.

14. Claims 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al. (US 3,995,444) and McKelvey et al. (EP 0 376 763) taken further in view of Armstrong et al. (US 6,238,908).

The combination of the references of Peterson and either Fahy or Clark et al. taken further in view of McKelvey et al. has been discussed above.

With respect to claims 60 and 61, the modified primary reference fails to disclose the use of transferable data with respect to the portable housing.

The reference of Fahy discloses the use of a microprocessor for data tracking (See column 16, lines 6-12), however, the reference does not disclose that the portable housing includes transferable data regarding the housing and its contents.

The reference of Armstrong et al. discloses that it is known in the art to provide a portable culture device with a memory device for interfacing the portable device with a plurality of different system devices (See column 10, line 58, to column 11, line 7, and column 15, lines 27-50).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with transferable data regarding the housing and its contents as is conventional in the art for transferring stored data between different system devices that interface with the portable housing.

15. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (US 3,810,367) in view of either Fahy (US 5,586,438) or Clark et al.(US 3,995,444) in view of Thomson (US 1,369,367) and McKelvey et al.(EP 0 376 763) taken further in view of Armstrong et al.(US 6,238,908).

The combination of the references of Peterson and either Fahy or Clark et al. and Thomson taken further in view of McKelvey et al. has been discussed above.

With respect to claims 62 and 63, the modified primary reference fails to disclose the use of transferable data with respect to the portable housing.

The reference of Fahy discloses the use of a microprocessor for data tracking (See column 16, lines 6-12), however, the reference does not disclose that the portable housing includes transferable data regarding the housing and its contents.

The reference of Armstrong et al. discloses that it is known in the art to provide a portable culture device with a memory device for interfacing the portable device with a plurality of different system devices (See column 10, line 58, to column 11, line 7, and column 15, lines 27-50).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the portable housing of the primary reference with transferable data regarding the housing and its contents as is conventional in the art for transferring stored data between different system devices that interface with the portable housing.

Response to Arguments

16. Applicant's arguments, see pages 11-13, filed 12/29/2008, with respect to the rejection(s) of claim(s) 1-50, 53 and 56-61 under 35 USC 102(b) and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Peterson (US 3,810,367).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB